

Remarks:

Claims 34-66 are pending in this application. Applicant has amended claims 34, 37, 50-52, 55, and 63-65 to clarify the present invention. Applicant respectfully requests favorable reconsideration of this application.

Applicant has amended the claims to bring their format and language more in line with standard U.S. format and language and to ensure that antecedent basis exists for all terms.

The Examiner rejected claims 34, 38-43, 49, 50-52, and 56-65 under 35 U.S.C. § 102(a) as being anticipated by WO 02/058550 to MacAdam et al. The Examiner rejected claims 35-37, 44-48, 53-55, 58, and 66 under 35 U.S.C. § 103(a) as being unpatentable over MacAdam et al. in view of U.S. published patent application 2002/0082510 to Toole et al.

MacAdam et al. does not disclose the present invention as recited in independent claims 34, 52, or 65 since, among other things, MacAdam et al. does not disclose cardiac analysis that includes comparing a P-wave from an ECG-signal of a patient to a reference P-wave acquired from the patient. Rather, MacAdam et al. discloses solving a problem of how to detect a P-wave from an ECG where a T-wave obscures the P-wave, to obtain the "derived" P-waves. MacAdam et al. discloses identifying P-waves to determine their origin. The derived P-waves are compared to a library of P-waves of known focal origin of different origin. Thus, MacAdam discloses comparing waves of different origins.

MacAdam et al. also does not disclose cardiac analysis that is focused on dynamic changes of a configuration of one type of wave, the P-waves, during ECG-signal acquisition. Rather, MacAdam et al. discloses identifying P-waves to determine their origin. MacAdam et al. is of interest if the P-waves so derived have the same focal origin. On the other hand, the present invention as recited in claims 34, 52 and 65 includes analyzing dynamic changes of the same normal, native P-wave from the sinus mode, which are of the same focal origin and do not need any derivation process.

MacAdam et al. only discloses making a comparison of waves to a library of waves for confirming their origin. The comparison is not in any way connected to analyzing dynamic changes of a P-wave whose origin is already known. Additionally, according to the present invention as recited in claims 34, 52, and 65, the focal origin of the P-wave under study is already known.

Additionally, MacAdam et al. does not relate to normal p-waves originating in the sinus node of the heart. Rather, MacAdam et al. discloses detecting and classifying various arrhythmias. Along these lines, MacAdam et al. discloses that in some focal arrhythmias the atrial heart tissue begins to beat very rapidly as the focal origin moves from the sinus node to an ectopic site. MacAdam et al. discloses a method and system to allow a practitioner to objectively compare derived p-waves to determine if they are emanating from the same focus, as described at page 3, lines 9-10, and page 4, lines 13-14. On the other hand, according to the present invention as recited in claims 34, 52 and 65, the dynamic morphological changes of the P-wave from the sinus node, not from any ectopic sites, are analyzed.

The Examiner asserts that MacAdam et al. discloses that the P-wave can be a valuable tool used by clinicians to diagnose the condition of the heart, and more precisely, in the diagnosis of atrial and ventricular arrhythmias, and is easily elicited by a 12-lead ECG-system, page 3, lines 3-6. This is an aspect of the prior art that is also mentioned in the present application, page 3, lines 2-4 and line 13. A unique aspect of the present invention as recited in claims 34, 52 and 65 is in the finding that instead of using P-wave in the detecting cardiac arrhythmias and using the 12-lead ECG-system, the present invention as recited in claims 34, 52, and 65 analyses dynamic changes of the configuration of normal P-waves originating from the sinus node.

Instead of using solely the 12-lead ECG-system that does not give a good three dimensional picture of the electrical waves, which neglects the small waves, for example the P-wave, the present invention may also use the three orthogonal leads, X, Y and Z, as described at page 3, lines 12-17, and page 4, lines 11-13.

The Examiner refers to page 8, lines 1-9, and page 13, lines 4-6, of MacAdam et al. as describing comparing a P-wave identified from an ECG signal to a P-wave with a previously captured reference template to discover whether or not the waves they have a common focal origin and so whether the templates differ from each other due to their different origin. However, every P-wave from a common origin has the same unchanged static configuration and template. A unique aspect of the present invention as recited in claims 34, 52, and 65 is in finding that the configuration of the P-wave from the sinus node, all the time from the same normal origin, is not unchanged and static. On the contrary the configuration of the P-wave can

change dynamically; it has a capability of a dynamic change. The New Oxford Dictionary of English defines "dynamic" as, "of a process or system characterized by constant change, activity or progress" and "static" as, "lacking in movement, action or change, especially in a way viewed as undesirable or uninteresting".

With respect to the present invention as claims 41, 42, 59 and 60, these claims recite how a detected P-wave may be averaged in the defined time period, at least one averaged P-wave may be used as an initial reference P-wave, and that upcoming averaged P-waves may be compared to the initial reference P-wave. MacAdam et al. does not disclose averaging. MacAdam et al. does not even utilize the word "averaging". Rather, MacAdam et al. disclose a method where a signal processor receives a first ECG signal from a signal sensing unit, thereby permitting a user to mark beginning and end points of the ECG signal for defining a reference template. MacAdam et al. disclose that then by acquiring data from multiple leads, a best fit between the reference template and the acquired data may be identified by using a correlation coefficient calculation. These aspects of MacAdam et al. are described at page 5, lines 13-18.

The Examiner asserts that MacAdam et al. disclose that is well known in the art to use a 12 lead ECG in an attempt to diagnose the arrhythmias. As recited in claims 49 and 62, the present invention may utilize three orthogonal leads, X, Y and Z, as described at page 3, lines 12-17, and page 4, lines 11-13.

A unique aspect of embodiments of the present invention is in the finding that instead of detecting "abnormalities," which is a common approach in the field of electrocardiography,

analysis of dynamic changes of the configuration of normal, one might say even uninteresting P-waves may be valuable. MacAdam et al. does not disclose this.

In view of the above, MacAdam et al. does not disclose all elements of the present invention as recited in claims 34, 38-43, 49, 50-52, and 56-65. Since MacAdam et al. does not disclose all elements of the present invention as recited in claims 34, 38-43, 49, 50-52, and 56-65, the present invention, as recited in claims 34, 38-43, 49, 50-52, and 56-65, is not properly rejected under 35 U.S.C. § 102(b). For an anticipation rejection under 35 U.S.C. § 102(b) no difference may exist between the claimed invention and the reference disclosure. *See Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 U.S.P.Q. 841 (C.A.F.C. 1984).

Along these lines, anticipation requires the disclosure, in a cited reference, of each and every recitation, as set forth in the claims. *See Hodosh v. Block Drug Co.*, 229 U.S.P.Q. 182 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir. 1985); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986); and *Akzo N.V. v. U.S. International Trade Commissioner*, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986).

The combination of MacAdam et al. and Toole et al. does not suggest the present invention as recited in claims 35-37, 44-48, 53-55, 58, and 66 since, among other things, Toole et al. does not overcome the above-discussed deficiencies of MacAdam et al. For example, Toole et al. does not suggest cardiac analysis that includes comparing a P-wave from an ECG-signal of a patient to a reference P-wave acquired from the patient or cardiac analysis that is focused on dynamic changes of a configuration of one type of wave, the P-waves, during ECG-signal

acquisition. Toole et al. suggests creating a model for a normal heart vector by measurements of healthy volunteers. An individual's heart vector is then compared to this "normalized" heart vector. Therefore, Toole et al. does not suggest comparing a P-wave from an ECG-signal of a patient to a reference P-wave acquired from the patient. Rather, Toole et al. suggests that a model representing a specific condition of heart disease can be created by measurements from a group of persons having this condition, and comparing the heart vector of an individual can be compared to this model. In both cases, the measurement data from the individual is compared with a general model, not with the measurement data from the same individual.

With respect to claims 35, 53, and 66, these claims recite monitoring dynamic changes of the PQ segment. Neither prior reference, and, in fact, no text book or any other document known to the Applicant prior to the date of invention relates to analysis of the dynamic changes of the PQ segment in course of time in one individual. Toole et al. only suggests at page 4-5 that the PQ sector is related to a sample of a specified grouping of persons. However, this suggests a totally different approach than the present invention as recited in claims 35, 53 and 66.

Both MacAdam et al. and Toole et al. suggests obtaining measurement data from an individual and comparing the obtained data with external data, which may be data from a data bank or a model. As a result, both MacAdam et al. and Toole et al. teach away from the present invention as recited in the claims, where, on the contrary, it is important to compare the data obtained from one individual. Both MacAdam et al. and Toole et al. are silent about the dynamic changes of the P-wave in particular.

In view of the above, the references relied upon in the office action, whether considered alone or in combination, do not disclose or suggest patentable features of the present invention. Therefore, the references relied upon in the office action, whether considered alone or in combination, do not anticipate the present invention or make the present invention obvious. Accordingly, Applicant respectfully requests withdrawal of the rejections based upon the cited references.

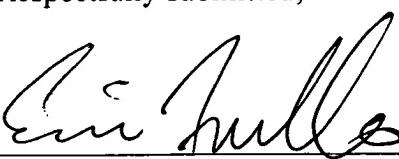
In conclusion, Applicant respectfully requests favorable reconsideration of this case and early issuance of the Notice of Allowance.

If an interview would advance the prosecution of this case, Applicant urges the Examiner to contact the undersigned at the telephone number listed below.

The undersigned authorizes the Commissioner to charge fee insufficiency and credit overpayment associated with this communication to Deposit Account No. 22-0261.

Respectfully submitted,

Date: 1/29/07


Eric J. Franklin, Reg. No. 37,134
Attorney for Applicant
Venable LLP
575 Seventh Street, NW
Washington, DC 20004
Telephone: 202-344-4936
Facsimile: 202-344-8300